K013055

DEC 0 7 2001

Summary of Safety and Effectiveness

Submitter's name, address, telephone number and contact person:

Bioplate, Inc.
6911 Melrose Avenue
Los Angeles, CA 90038
(323) 549-9500
(323) 935-0110 (fax)

Contact Person: Carol E. Jones

Trade Name of Device

The Bioplate® Bioclip® Craniotomy Fixation System

Common name

Bone Plate

Classification name

Bone Plate

Device Classification

76 JEY (21CFR – 872.4760)

Predicate Devices

The Bioplate® Bioclip® Craniotomy Fixation System -(K001530) (K002879) (K011380)

Description of the device

The Bioplate® Bioclip® Craniotomy Fixation System consists of a bone plate manufactured of 6Al 4V titanium alloy that utilizes a combination of fastening tabs and spring action to re-attach a cranial bone flap following a craniotomy procedure. Each device is provided non-sterile and must be sterilized prior to use. The device is intended for single use only and may be combined only with other titanium and titanium alloy implants.

Intended used of the device

The Bioplate® Bioclip® Craniotomy Fixation System is intended to reattach a cranial bone flap to the surrounding cranium after a craniotomy procedure. Each device is intended for single use only and only in conjunction with other titanium and titanium alloy implants.

The Bioplate® Bioclip® Craniotomy Fixation System is contraindicated in the following conditions:

The gap in the cranial bone is greater than 2.5mm for standard sizes.
The gap in the cranial bone is greater than 4mm for XT sizes.
The skull thickness is less than 4.5mm

Comparison of the devices' technological characteristics with those of predicate devices

The Bioplate® Bioclip® Craniotomy Fixation System has the same indications for use as the predicate devices marketed by Bioplate, Inc. All of the technical characteristics of The Bioplate® Bioclip® Craniotomy Fixation System are substantially equivalent to the corresponding characteristics of the predicate devices, and any minor differences raise no new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 7 2001

Ms. Carol E. Jones
Executive Vice President
Bioplate, Incorporated
6911 Melrose Avenue
Los Angeles, California 90038

Re: K013055
Trade/Device Name: The Bioplate Bioclip Craniotomy Fixation System
Regulation Number: 872.4760
Regulation Name: Bone Plates and Bone Screws
Regulatory Class: II
Product Code: JEY
Dated: September 11, 2001
Received: September 11, 2001

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPLICANT: Bioplate Inc.

510(k) NUMBER: (if known): K013055

DEVICE NAME: Bioplate® Bioclip® Craniotomy Fixation System

INDICATIONS FOR USE:

The Bioplate® Bioclip® Craniotomy Fixation System is intended to re-attach a cranial bone flap following a craniotomy procedure. The clip/plate is used to align and stabilize bony tissue while normal healing occurs. Each device is intended for single use only and may be combined only with other titanium and titanium alloy implants.

The Bioplate® Bioclip® Craniotomy Fixation System is contraindicated in the following conditions:

The gap in the cranial bone is greater than 2.5mm for standard sizes.
The gap in the cranial bone is greater than 4mm for XT sizes.
The skull thickness is less than 4.5mm

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K013055